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| APPLICATION NO. | FILED DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|------------|----------------------|---------------------|------------------|
| 09/381,828 | 11/24/1999 | ROLF SKOLD | 2964-102P | 4478 |
| 7590 | 11/04/2004 | | EXAMINER | |
| BIRCH STEWART KOLASCH & BIRCH | | | SODERQUIST, ARLEN | |
| PO BOX 747 | | | ART UNIT | PAPER NUMBER |
| FALLS CHURCH, VA 220400747 | | | 1743 | |
| DATE MAILED: 11/04/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------|--------------|------|
| Office Action Summary | Application No. | Applicant(s) | S.C. |
| | 09/381,828 | SKOLD, ROLF | |
| | Examiner | Art Unit | |
| | Arlen Soderquist | 1743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 July 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-8 and 10 is/are rejected.
- 7) Claim(s) 3 and 9 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 24 November 1999 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

1. In view of the Appeal Brief filed on July 6, 2004, PROSECUTION IS HEREBY REOPENED. New grounds of rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

2. Claim 5 is objected to because of the following informalities: "with" is not correctly spelled in the last line of the claim. Appropriate correction is required.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-2, 4-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franchini in view of Rouse (newly cited and applied), Baxter and Cunha or Renoe and Bader, Laughlin, Li, Rodriguez or Saxberg. In the paper Franchini teaches an approach to the problem of the dependence of the dissociation constant of weak electrolytes on the temperature and on the solvent composition in the ethane-1,2-diol-2-methoxyethanol solvent system. This empirical approach to clarify the problem of the dependence of the dissociation constants of weak

electrolytes on temperature and composition of mixed solvents systems (X) is applied to the dissociation constant of picric acid in ethane-1,2-diol, in 2-methoxyethanol and in their binary mixtures. The data are those of previous work (recalculated by means of the more accurate Fuoss-Hsia equation) integrated by the experimental data relative to 3 new mixtures. Two equations of the dependence of K on T and of K on X, respectively, were suggested and good accordance between experimental and calculated values are shown. Starting from the 2 above-mentioned equations, general empirical equations for the surface K(T,x) are proposed; the average difference between calculated and experimental K values is ~8%. A three-dimensional plot of the function $K = K(T,X)$, figure 3, phase diagram) is presented. In the procedure section of page 1698, Franchini teaches that the solutions of picric acid of different concentrations were made by successive dilution of stock solutions. Franchini does not teach automated control of the dilutions in a single container.

In the paper Rouse teaches automation of phase diagram recording. An automated titration system was developed for generating data to construct phase diagrams, which are extremely useful in the development of personal and household products. The authors describe the system and how it can be used to perform dual titration. A clear microemulsion sample is titrated with an oil until the dispersion turns cloudy (defined to be a transmittance < 90%). This mixture is then dosed with a certain quantity of cosurfactant, more than enough to clear the mixture. The sample is again titrated with oil. This process continues until the sample no longer clears upon adding cosurfactant. The resulting measurements of oil uptake can be used to characterize the boundaries of the L1 or oil-in-H₂O microemulsion region of the phase space. Experiments for up to sixteen samples can be performed, each having individual setup and operating instructions. Features include completely automated operation, computer-controlled 2-speed mixing, viscosity detection at the end-point condition, and the storage of results in a computerized format. Figures 1 and 6-7 show multidimensional representations of the data. From the experimental section it is clear that the device and method use a single vessel to which additions of a solution that changes the concentration of at least one of the components is added in increments.

In the abstract Baxter evaluates a simplified generalized standard additions method for calibration in the direct analysis of solid samples by graphite furnace atomic spectrometric

techniques. In combining the principles of experimental design and the simplified approach to the generalized standard additions method, a useful calibration strategy was obtained for the single-component analysis of solid samples. By varying both the solid sample mass and the amount of analyte added, the observed response is defined by these 2 variables and may be geometrically described as a surface in 3-dimensional space. The use of multiple regression techniques then allows the analyte concentration in the solid to be computed from the response plane. Simultaneous blank correction and quantification was also performed. The importance of a well designed experimental lay-out and the effects of random errors or noise on the accuracy of the procedure were investigated, and some analytical results are given in the paper. The approximation of the analyte concentration obtained is fairly insensitive to curvature in the calibration function, but tends to be biased high in the presence of intense noise. This latter is a major limitation given the inhomogeneity of most solid samples which leads to irreproducible or noisy results.

In the paper Cunha discusses automated gravimetric management of solutions with a high-performance microcomputer-controlled gravimetric burette. A versatile gravimetric burette and the necessary interface that allows it to be controlled by an IBM-PC microcomputer are described. The burette employs an electronic balance that holds three 30 mL flasks. The flasks are used for delivering different titrants or standard solutions and are connected to the sensor through the bottom of the balance. The addition of the solution is controlled by poly(tetrafluoroethylene) electromechanical valves housed inside the unit. The flasks can be refilled automatically from larger reservoirs placed outside the case. Solution level sensors are used to realize automatic refill when necessary. The mass delivered from the flasks is read by the computer through an RS232C interface. The burette can, when driven by the appropriate software, perform potentiometric, biamperometric and spectrophotometric titrations, standard additions procedures and the preparation of standard solutions.

In the paper Renoe presents an automated computer-controlled solution handling system utilizing weights. An automated sample and reagent solution preparation system, which is generally applicable in the analytical laboratory, was designed and tested. The new system utilizes an electronic sensor to weigh accurately the nominal aliquots of sample and reagent solutions that are added to a disposable beaker. Each plastic beaker on a turntable is

automatically positioned on the weight sensor. Reagent and sample solutions are added by gravity feed for selected time intervals to provide nominal amounts. Each reagent or sample is accurately weighed after addition, and the beaker is then automatically moved to a stirring station while another beaker is moved into position for weight measurements. The amounts of reagents added to the beaker can be incrementally adjusted as desired. The operational modes are specified by interaction through FORTRAN programming and FORTRAN callable subroutines, which control or accumulate data concerning the system turntable, weight sensor, solution delivery devices and mixer, and the computer peripherals. The analytical utility of the system is demonstrated by data obtained in automated preparation of working curves and standard-addition procedures.

In the paper Bader presents a systematic approach to standard addition methods in instrumental analysis. Standard addition procedures in instrumental analysis are described, and variations possible with linear and nonlinear instruments are listed. Variations for linear instruments include continuous variation of standard at constant total volume, of unknown at constant total volume, of both unknown and standard at constant total volume, variable volume single addition of standard, and variable total volume with continuous variation of standard. An example of a nonlinear response and examples of radiochemical techniques are also presented. In the first paragraph Bader teaches that the standard additions methods overcome or eliminate problems due to the calibration being performed with different sample matrices and differences in instrumental response. Relative to the instant claims case 5 (page 704) is important in that a single sample has multiple additions of a standard solution of the analyte. This case teaches that this method is particularly applicable to polarographic methods by reducing disturbances to the system and reducing the time for analysis due to changing of samples. Case 6 shows how case 5 can be applied to non-linear experiments.

In the paper Laughlin presents an expedient technique for determining solubility phase boundaries in surfactant-water systems. A stepwise dilution method is described for determining solubility limits in surfactant-H₂O systems. Only 1 g of sample and 1 day are required to obtain reliable results. Special problems such as foaming and viscous liquid crystal phases can be dealt with. However, inner transitions involving liquid crystals are beyond the scope of the method. Samples are viewed between crossed polarizers to determine phase transition temperatures on

cooling. Aliquots of H₂O are added to the original sample and measurements are repeated. In the first paragraph of the paper Laughlin teaches that prior techniques for measuring these phase boundaries require a lot of sample and effort which is not practical with small valuable research samples. These prior methods follow one of two principles of which they modified the synthetic method to arrive at the above stepwise dilution method. The procedure is found in the paragraph bridging the columns of page 239. Figure 2 shows a phase diagram determined by the technique.

In the paper Li presents a computer approach to ion-selective electrode potentiometry by two standard additions and subtractions methods through ionic strength calibration. The effect of ionic strength in standard additions and subtractions methods has been utilized for determining an unknown concentration using an ion-selective electrode without prior calibration of the electrode. In the simplest instance, only 2 standard additions or subtractions are required. An initial value of unknown concentration or electrode slope is first assumed to solve the equations repeatedly. This method gives greater accuracy than the methods which are used at present. The method was used to evaluate the unknown concentration and electrode slope. The blank solution has the same ionic strength as the standard solution in the 2 standard additions method. In the 2 standard subtractions method, a suitable blank solution is chosen. The effectiveness of computer iterative solution of the 2 standard additions method is demonstrated on a lead sample.

In the paper Rodriguez discusses validation of an analytical instrumental method by standard addition. A statistical procedure to validate an analytical methodology by standard addition methodology is described. The data set obtained in 3 calibration experiments with standard dilutions, standard additions, and portions of sample was used. The accuracy of the analytical results is checked by comparison of analyte contents in the different calibrations and from the recovery. Mathematical expressions to estimate the statistical parameters are proposed. The statistical protocol was applied to fluorometric determination of Mo with alizarin S in vegetable tissues. In the experimental section of page 472 Rodriguez discusses the procedures used for the standard calibration -- different analyte standard solutions and replicates of each solution-- and the standard addition calibration -- continuous variations of standard at constant volume. It is clear that the standard additions method does not require replicates.

In the paper Saxberg presents a generalized standard addition method. The normal standard addition method assumes that for any 1 analyte in a sample there is an analytical sensor

which responds to that analyte and no other component in the sample. When the analytical sensor is not completely selective, so-called interference effects result which can be a major source of error. The generalized standard addition method (GSAM) provides a means of detecting interference effects, quantifying the magnitude of the interferences, and simultaneously determining analyte concentrations. The GSAM as presented in the paper uses multiple linear regression to analyze multicomponent samples where the response-analyte concentration relation is of some arbitrary polynomial form; for a nonlinear polynomial relation, an iterative solution is required. In the first paragraph of the paper, Saxberg teach that the standard addition method is well known to all analytical chemists along with its use to overcome sample and/or method associated interferences such as residual matrix effects. the second paragraph teaches that in the method a linear change in the response of the analyte is assumed. Thus plotting the response change for several successive additions of the analyte to a sample with an unknown analyte concentration allows the analyte concentration to be found.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the successive dilutions of Franchini with the successive additions of an analyte containing solution of known concentration according to the teachings of Rouse, Bader, Li, Rodriguez or Saxberg because of the reductions of interferences due to matrix effects and the greater accuracy through use of a standard additions method as taught by Bader, Li, Rodriguez and Saxberg. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the successive dilutions of Franchini with the stepwise dilutions of an analyte containing solution according to the teachings of Laughlin or Rouse because of the reductions time, effort and sample as taught by Laughlin or the ability to map out a property as taught by Rouse. Additionally one of skill in the art would have recognized that as taught by Baxter the standard additions method is capable of being performed with two independent variables and one dependent variable with the result being plotted as a three-dimensional graph. It would have been obvious to one of ordinary skill in the art at the time the invention was made to automate the Franchini method through use of an automated liquid handling system as taught by Cunha, Rouse or Renoe because of the flexibility and versatility of liquid handling as taught by Cunha and Renoe or the ability to overcome the tedious nature of the process as taught by Rouse. Additionally the Courts have held that providing a mechanical or automatic means to

replace manual activity which accomplishes the same result is within the skill of a routineer in the art (see *In re Venner*, 120 USPQ 192 (CCPA 1958)).

5. Claims 1-2, 4-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over in Rouse view of Ajith and Inoue (all newly cited and applied). In the paper Rouse teaches automation of phase diagram recording. An automated titration system was developed for generating data to construct phase diagrams, which are extremely useful in the development of personal and household products. The authors describe the system and how it can be used to perform dual titration. A clear microemulsion sample is titrated with an oil until the dispersion turns cloudy (defined to be a transmittance < 90%). This mixture is then dosed with a certain quantity of cosurfactant, more than enough to clear the mixture. The sample is again titrated with oil. This process continues until the sample no longer clears upon adding cosurfactant. The resulting measurements of oil uptake can be used to characterize the boundaries of the L1 or oil-in-H₂O microemulsion region of the phase space. Experiments for up to sixteen samples can be performed, each having individual setup and operating instructions. Features include completely automated operation, computer-controlled 2-speed mixing, viscosity detection at the end-point condition, and the storage of results in a computerized format. Figures 1 and 6-7 show multidimensional representations of the data with figure 7 being a contour plot. From the experimental section it is clear that the device and method use a single vessel to which additions of a solution that changes the concentration of at least one of the components is added in increments. Rouse does not teach temperature as an independent variable.

In the paper Ajith discusses the effect of NaCl on a nonionic surfactant microemulsion system. Various types of microstructure and macroscopic phase changes of the pseudoternary system alkane/Brij 35 + propanol/H₂O (studied in the presence of different amounts of NaCl at different temperatures) are described. Viscosity and conductance studies reveal that the system at 80% surfactant (S) (where S indicates Brij 35 and 1-propanol together) probably exists as a bicontinuous microemulsion at all H₂O fractions even in the presence of NaCl. In the presence of NaCl, the pseudoternary phase diagrams of these systems change with change of temperature. Increasing the concentration of NaCl brings down the Winsor I → III transition temperature and at 2.5 M NaCl, the system exists as Winsor III along the entire range of temperature studied (30-

70°). However a Winsor III → II transition was not observed in this case in this temperature range and also within the NaCl concentration range studied. The cloud point of the microemulsions and the contact angle of these systems with a Teflon surface were also determined. The contact angles indicate similar structure over the entire range of oil/H₂O ratios. Figure 9 is a three dimensional diagram. The materials and methods section on page 1122 teaches that the phase diagrams were determined based on a titration method. This section also discusses the cloud point determinations and the use of a bath to control the temperature to determine both clouding and declouding.

In the paper Inoue discusses aggregation behavior of hexaethylene glycol decyl ether/dipalmitoylphosphatidylcholine mixture in aqueous dispersion. The mixture of hexaethylene glycol decyl ether (C10E6) and DPPC assumes diverse aggregation states in aqueous dispersion, depending on the composition and temperature. Accordingly, the vesicle-to-mixed-micelle transformation occurring in this system exhibits a remarkably different behavior below and above 35.5°. The phase diagram of the aqueous C10E6/DPPC mixture was constructed based on the turbidity, quasi-elastic light scattering, and DSC measurements. The characteristic feature of this system is the appearance of a phase separation region, analogous to the phenomenon observed in aqueous solutions of polyoxyethylene-type nonionic surfactants at temperatures above the cloud points. The temperature-induced reversible transformation between mixed micelles and vesicles is also an interesting feature of this system, which has rarely been observed in other aqueous dispersions of surfactant/phospholipid mixtures. The materials and methods section of page 312 teaches that the turbidity measurements are made by increasing the concentration in a successive stepwise manner with the concentrations being calculated from the initial concentrations. This section also discusses the measurements relative to varying temperature using a Peltier-type temperature controlling system and a platinum resistance thermometer. Figures 3 and 5 show diagrams relating the temperature, concentration and turbidity. Figure 4 shows heating and cooling curves.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Rouse device and method with means and steps to include temperature as an independent variable as taught by Ajith and Inoue because of the increased ability to characterize the emulsions and their phase diagrams as shown by Ajith and Inoue.

6. Claims 3 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The art of record does not teach or fairly suggest the method as claimed in which a volume of tested sample is replaced by an equal volume of liquid having the analyte at a concentration different than the tested sample to form a new sample for testing or an apparatus as claimed which has means to control the apparatus to perform the method of claim 3.

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The newly cited and applied art clearly teaches apparatus and method in which the concentrations are changed by adding a solution of different concentration to the original sample container with successive or incremental additions and measuring a dependent property. The dependent property being stored and ultimately being used to produce a multidimensional diagram. The Rouse reference in particular is directed to an apparatus and method in which this occurs in a totally automated manner. Another significant aspect of this reference is that it appears to be directed at the type of liquids and diagrams that the instant specification is directed toward (see pages 1 and 5-6 of the instant specification).

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited reference deal with automated control of solution additions or property measurement. They also deal with the production of phase diagrams.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose current telephone number is (703) 308-3989. After about December 16, 2003, this number will change to (571) 272-1265 as a result of the examiner moving to the new USPTO location. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311 (after-final), 703-305-7718, 703-305-5408 and 703-305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Arlen Soderquist
Arlen Soderquist
October 28, 2004

ARLEN SODERQUIST
PRIMARY EXAMINER

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